JUN 27 2008

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510(k) Summary
Biomet Phoenix™ Ankle Nail System

Preparation Date: June 25, 2008

Applicant/Sponsor: Biomet Trauma (aka EBI; names may be used interchangeably)
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Debra L. Bing

Proprietary Name: Biomet Phoenix™ Ankle Nail System

Common Name: Intramedullary fixation rod

Classification Name: Rod, Fixation, Intramedullary and Accessories (21 CFR 888.3020)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Acid Etched Lag Screws	K070955	Biomet Trauma
Tibial Locking Nail System	K063570	Biomet Trauma
Ankle Arthrodesis Nail	K021786	Biomet, Inc.
UltiMax Ankle Fusion Rod	K991790	Encore Orthopedics, Inc.

Device Description:
The Biomet Phoenix™ Nail System is an intramedullary nail system comprised of Ti-6Al-4V and UHMWPE.

Indications for Use:
The Biomet Phoenix™ Ankle Nail System is indicated for tibiotalocalcaneal arthrodesis (fusion).

Specific indications include:
1. Avascular necrosis of the talus
2. Failed total ankle arthroplasty
3. Trauma (malunited tibial pilon fracture)
4. Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
5. Revision ankle arthrodesis
6. Neuroarthropathy
7. Rheumatoid arthritis
8. Osteoarthritis
9. Pseudoarthrosis

Biomet Trauma
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300 tel
973-257-0232 fax

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Summary of Technologies:
The technological characteristics (materials, design, sizing) of the Biomet Phoenix™ Nail System are similar or identical to the predicate devices.

Non-Clinical Testing: Engineering analyses comparing the Biomet Phoenix™ Nail System to a predicate device were conducted to determine substantial equivalence. The results indicated that the Biomet Phoenix™ Nail System was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

All trademarks are property of Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Biomet Manufacturing Corp.
% Ms. Susan Alexander
Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K081243
Trade/Device Name: Biomet Phoenix Ankle Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: April 29, 2008
Received: May 1, 2008

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081243

Device Name: Biomet Phoenix™ Ankle Nail System

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8. Osteoarthritis
9. Pseudoarthrosis

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081243